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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/421,106	10/15/1999	Joseph R. Byrum	04983.0119.C	3645

28381 7590 09/20/2002

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EXAMINER	
KIM, YOUNG J	
ART UNIT	PAPER NUMBER
1637	21

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/421,106	Applicant(s) BYRUM, JOSEPH R.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Sequence Compliance NoticeSequence Homology Search.

DETAILED ACTION

Applicants are advised that the finality of the previous Office Action mailed on August 29, 2001 has been withdrawn and the prosecution on its merits has been reopened.

Preliminary Remark

Applicants are advised that claims 17 and 18, which are directed to an invention that is independent or distinct from the invention originally claimed (as noted in the previous Office Action mailed on August 29, 2001), remain withdrawn from consideration as being directed to a non-elected invention See 37 CFR 1.142(b) and MPEP 821.03.

Specification

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set for in 37 CFR 1.82(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 because on specification page 80, lines 1-15, a nucleic acid sequence of more than 10 nucleotides in length is disclosed without a proper SEQ ID Number (See also the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures). Applicants are advised to peruse through the specification to identify any nucleic acid sequences that are 10 or more nucleotides in length (or amino acid sequences that are more than 4 contiguous in length) are identified by SEQ ID Numbers for complete compliance.

A fully responsive communication MUST comply with the sequence rules.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the first nucleic acid sequence." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 1-9 and 16 under 35 U.S.C. 101 [because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility], made in the Office Action mailed on August 29, 2001 is maintained for reasons of record.

Applicants' arguments received on April 30, 2002 (brief) have been fully considered but they are not found persuasive.

Applicants argue that the claims satisfy the requirements under the 101 statues because the claimed nucleic acids (and vectors comprising them) are useful in detecting the

presence/absence of polymorphisms (Brief, pp. 5, bottom), as probes for expression profiling (Brief, pp. 5, bottom), or as a tool for screening possible herbicide compounds (Brief, pp. 6).

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is not a reward for the search, but compensation for its successful conclusion.

These utilities are considered to be non-substantial as set forth in the previous Office Action because the nucleic acids, by their presence or absence, or as probes, do not provide a real-world applicability to one ordinarily skilled in the art. The nucleic acids as disclosed, do not provide to one of ordinary skill in the art, what the presence or the absence of the claimed nucleic acids would be useful for. For a nucleic acid to have a **substantial or real-world** utility, its presence or absence must relay to the ordinarily skilled artisan a real-world applicable information, such as detection/predisposition of certain conditions (i.e., cancer markers) (emphasis added). A statement indicating that the nucleic acids have substantial utility because they contain polymorphisms would not give an **immediately apparent**, or substantial utility as court has expressed because such apparent utility would not be found without conducting further research on each of the claimed polymorphisms (emphasis added).

Appllicants' arguments drawn to the claimed nucleic acids being useful as probes are not found persuasive as set forth in the previous Office Action because any piece of nucleic acid, by its inherent property, would hybridize to its complement. However, hybridization of such nucleic acid must relay to an ordinarily skilled artisan some real-world applicability. A nucleic acid could certainly be used as for example, a probe for detecting a condition, a primer for amplifying a region which would serve as an indication of something, determining the location of a corresponding DNA sequence on a physical or genetic map and thus determine the function of a gene, etc. However, the claimed nucleic acids lack a substantial utility because the specification of the instant application fails to provide any guidance that the presence/absence of the claimed nucleic acids correlate some disease, condition, or presence of harmful agents (i.e., bacteria), etc. The instant application simply relies on the fact that the probes have been patentable in the art and since the claimed nucleic acids can be used as a probe, it must be patentable. Such argument is not found persuasive because nucleic acid probes are not patented solely on their ability to hybridize to their complement. It is the information (a specific benefit, or an immediately applicable benefit) which is derived from the hybridization. Applicants also argue that the probes could be used for expression profiling. It is true that a probe would be found to have an immediately apparent utility if by its over-expression or under-expression, an artisan could derive a useful information (such as diagnostic for conditions). However, Applicants fail to disclose any of such benefit. The artisan using the nucleic acids of the Applicants would not know why the artisan should use the claimed nucleic acids over any other polymorphic nucleic acids that are isolated from plants. Without conducting further research, the

artisan would not have any reason, such as an immediately apparent benefit, to use the claimed polymorphic nucleic acid over other polymorphic nucleic acids isolated from plants.

It is noted that Applicants' attempt to attribute utility to the claimed polynucleotides through use of a microscope analogy. A microscope, by virtue of the invention, has a real world application in magnifying microscopic objects (that are known to exist) to which the human eyes are not capable of seeing. The real world application of a nucleic acid, however, does not lie in its inherent property of hybridizing to any template. The nucleic acid, by its hybridization or amplification, must infer useful information. It is that useful information (immediately useful benefit) which would give the nucleic acid a substantial utility. The instant application has failed to disclose such information to the artisan. Applicants also state that the use of the claimed nucleic acid molecules to detect the presence or absence of polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. This argument is not found persuasive because an artisan will be led to use a gas chromatograph for identifying, via separation, the contents of a particular element(s) in the gas, an immediately apparent benefit to the artisan. However, Applicants have not given any immediately apparent benefit (or substantial utility) for the artisan to use the claimed polymorphism over any other polymorphisms isolated from plants. An immediately apparent benefit that would lead the artisan to use a polymorphic nucleic acid would be, for example, cancer diagnostic (mutations in BRCA1 and BRCA2 which increases the likelihood of breast and ovarian cancer). Such disclosure would allow the artisan to realize the immediate benefit of using such polymorphisms over any other polymorphisms. The Applicants have failed to disclose such immediate benefit other than a laundry list of possible benefits that a nucleic acid could be used for.

It is noted that Appellants' attempt to attribute utility to the claimed polynucleotides through the use of a golf club analogy. In accordance with the Appellants' example, the golf club is useful and has utility in hitting a "golf ball," not any object. Its utility lies in hitting a golf ball. Similarly, the utility of a nucleic acid lies in what information it infers. Such information could be, "what does the presence/absence of the nucleic acid indicate," "what region does the nucleic acid amplify that gives significance," "what's the function of its encoded protein," etc. The instant application has failed to give such guidance to the artisan.

Appellants' arguments drawn to the claimed nucleic acid being useful for screening herbicide compound is not persuasive. Any expressed nucleic acid (ESTs) isolated from a particular source could be used in an expression study. However, the claimed nucleic acid, at best, would require of the skilled artisan conduct **further research** to find an immediate real-world applicable utility (emphasis added). If a nucleic acid was derived from a subtractive library (i.e., cancer), then the expression of a particular nucleic acid would give immediate utility to an ordinarily skilled artisan – to use it as a cancer diagnostic tool. However, any nucleic acid would not give this immediate real-world utility to the artisan because none of the claimed nucleic acids are disclosed as having this immediate real-world applicability. The instant application fails to give any guidance to the artisan what immediate real-world applicable (or substantial) utility would arise when the claimed nucleic acid are expressed or differentially expressed.

With regards to Applicants' argument drawn to the polymorphism having specific utility, any piece of nucleic acid is "specific" to its complement. However, the claimed nucleic acids lack substantial utility as discussed above.

For the foregoing reasons, the utility rejection under 35 U.S.C. 101 is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-9 and 16 under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above one skilled in the art would not know how to use the claimed invention is maintained.

Applicants' arguments have been fully considered, but as set forth above, the utility of the claimed nucleic acids is determined to be not established and thus, the rejection is maintained.

The rejection of claims 1-9 and 16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants argue that Applicants have provided the nucleotide sequences required by the claims, e.g., SEQ ID Nos: 1-10, vectors comprising these nucleotide sequences, and bacterial artificial chromosomes comprising these nucleotide sequences, and thus established possession of the claimed invention.

This argument is not found persuasive because the claims are directed to a nucleic acid **hybridizing** to a second nucleic acid **having** (or comprising) a nucleic acid sequence selected from a group consisting of SEQ ID NO: 1-10, and vector comprising them, etc (emphasis added).

The issue at hand is whether or not the nucleic acid is properly described under the 112, first paragraph.

First of all, SEQ ID Numbers 1-10 **do not** contain a complete open reading frame (emphasis added). Despite this fact, the claims recite the use of second nucleic acids that **comprise** the SEQ ID numbers, reading on the use of second nucleic acids that would be a full-length cDNA and possibly a gene (if the SEQ ID Number is from a single exon). Therefore, the claims read on use of nucleic acid sequences that are not described.

Second, the claims are drawn to a nucleic acid that hybridizes to a second nucleic acid. As noted above, because the second nucleic acid does not contain a full open reading frame, the claims would read on a full-length cDNA sequences as well as gene sequences that would hybridize to the second nucleic acid. According to the Written Description guideline, example 7 (see Attached), such claims read on an a full-length cDNA and gene containing regions undescribed by the Applicants, rendering the claims improperly described under 112, first paragraph.

Appellants are advised that the rejection is being maintained in accordance with the PTO technology center guidelines.

Claim Rejections - 35 USC § 102

The rejection of claim 4 under 35 U.S.C. 102(b) as being anticipated by Laten et al. (SEQ ID NO: 8), in the Office Action mailed on August 29, 2001, is withdrawn in view of the arguments presented in the Brief received on April 30, 2002 and in careful reconsideration

.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Laten et al. (SEQ ID NO: 8) is maintained.

Applicants' argument drawn toward Larkens et al. reference is noted. Examiner assumes that the arguments drawn to Larkens et al. reference resulted from the typographical error present in the Final Office Action mailed on August 29, 2001. In the Final Office Action mailed on August 29, 2001, claims 1 and 4 were rejected under Larkens et al. reciting that Larkens et al. disclosed a nucleic acid sequence that exhibited 63.8% local homology to SEQ ID Number 8, when in fact the claims should have been rejected over Laten et al. which disclosed a nucleic acid sequence that exhibited 94.2% local similarity match to SEQ ID Number 8. This typographical error is evident because the Larkins et al. rejection had been withdrawn in the Final Office Action mailed on March 14, 2001.

As to the rejection of claim 1 in view of Laten et al. reference, Applicants' arguments are not found persuasive because Laten et al. disclose a nucleic acid (308 base pairs) having 94.2% homology to the nucleic acid of SEQ ID Number 8. In response to Applicants' arguments

stating that no scientific evidence was given for the basis of this rejection, melting temperature of the cited nucleic acid had been calculated based on the formula (pp. 269, formula number 5) disclosed in Meinkoth et al., "Hybridization of nucleic acids immobilized on solid supports," (Analytical Biochemistry, 1984, vol. 138, pp. 267-284). The melting temperature of the cited nucleic acid was calculated under the most stringent wash condition set forth in the claim (2.0x SSC at 50^{O}C). The salt concentration (in molarity) was calculated based on the disclosure by Meinkoth et al. (pp. 267, footnote), resulting in 0.33 M of sodium concentration. The resulting melting temperature was calculated to be 72.1^{O}C. Based on this calculation, the cited nucleic acid has a melting temperature that is above the claimed wash temperature, thus fully capable of being hybridized to nucleic acid of SEQ ID Number 8, rendering the claim anticipated.

Therefore, for reasons set forth above, although Applicants' arguments have been fully and carefully considered, they are not found sufficient to rebut the prima facie case of rejection under 35 U.S.C. 102(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 09/521,640. Although the conflicting claims are not identical, they are not patentably distinct from each for the following reasons.

Claim 1 of the instant application is drawn to an isolated nucleic acid that specifically hybridizes to a second nucleic acid molecule having a nucleic acid sequence from SEQ ID NO: 1-10 while claim 1 of the '640 application is drawn to an isolated nucleic acid comprising from about 30 to about 300 nucleotide residues wherein the nucleic acid exhibits complete complementarity to a nucleic acid molecule having a nucleic acid sequence from SEQ ID NO: 1-304701. According to the sequence homology search, SEQ ID Numbers of the instant application is identical to the SEQ ID Numbers of the '640 application as follows:

Instant application	'640 application
SEQ ID NO: 1-10	SEQ ID NO: 141334-141343

Therefore, although the claims are not verbatim, both claims are drawn to nucleic acids that hybridize (since complementary) to the nucleic acids of identical SEQ ID Numbers, rendering the claims subject to the instant provisional double patenting rejection. As to the dependent claims 2-7 of the instant application, the claims are verbatim to the dependent claims 2-7 of the '640 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/15/02

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